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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,514	04/25/2005	Christophe Galopin	102790-131 (30070 US/2)	7074

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EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
09/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,514	GALOPIN ET AL.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/25/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The restriction requirement has been withdrawn. Claims 1-18 are pending.

Claims

Claim Rejections - 35 USC § 112 – Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-10, 13 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "consisting essentially" is inadequately described by the instant specification, since it fails to contemplate the exclusion of any particular ingredients as implied therein; nor does it provide any criteria for determining if a given ingredient "materially affects the basic or novel characteristics of the invention".

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf (WO 99/13734 already of record) in view of H&R (Frescolat Cooling Ingredients 1999).

Wolf discloses compositions comprising cooling flavors. The flavors may comprise about 3% to about 25% by weight of more than one physiological cooling agent. These include menthyl lactate, acyclic carboxamide, N-substituted p-menthane carboxamide and mixtures thereof (page 7, lines 15-22). The preferred cooling agents include WS-3, which encompasses menthol carboxamide[1] of the instant claims, and menthyl lactate (page 18, lines 20-30). The concentration of the physiological cooling agent will depend on the intensity of the physiological cooling agent and the desired cooling effect. The reference also discloses that combinations of cooling agents may have synergistic effects (page 22, lines 5-7). The cooling agents are made into a solution before further processing into a composition. This includes a solution of about 5% to 30% cooling agent. Higher levels may be used if higher temperatures are used. Generally water is used as the solvent but other solvents like alcohol should also be used (page 25, lines 8-16). The reference differs from the instant claims insofar as it does not disclose an example comprising WS3 and menthyl lactate or that the menthyl lactate is first liquefied.

H&R disclose menthyl lactate is Fresoclat ML. Menthyl lactate is oil soluble and is a very effective active cooling ingredient for use in cosmetic and

[1] Chemical Book, http://www.chemicalbook.com/ChemicalProductProperty_EN_CB0252522.htm, retrieved August 29, 2009. The reference discloses menthol carboxamide is WS-3 and N-ethyl p-methanecarboxamide.

food products. Frescolat ML should be melted at a temperature of around 50-60°C. It may also be dissolved in a solvent such as propylene glycol (page 6). The reference differs from the instant claims insofar as it does not disclose solutions comprising menthol carboxamide with the menthyl lactate.

Although the references do not disclose an example of a solution comprising menthyl lactate and menthol carboxamide, the reference suggest a composition comprising the two components. It would have been obvious to one of ordinary skill in the art to have made the suggested solution by melting menthyl lactate before adding it to menthol carboxamide and a solvent motivated by the desire to use a method that is disclosed in the art and is suggested by the manufacturer of menthyl lactate. By using the method of the combined teaching, it is reasonable to conclude the limitation that the concentration of menthyl lactate is higher than menthyl lactate when dissolved in a solvent is met because the concentration is dependent on the melting step.

In regards to claims 2 and 3, selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. Selection of any order of mixing ingredients is prima facie obvious. See MPEP 2144.04. The secondary reference teaches that menthyl lactate should be melted first. It would have been obvious to have added the solvent and menthol carboxamide to the melted menthyl lactate in any order absent of new or unexpected results as supported by MPEP 2144.04.

In regards to claims 4, 7, 14, 15 and 18, H&R disclose propylene glycol as a suitable solvent for dissolving menthyl lactate. Generally, it is *prima facie*

obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used propylene glycol as the solvent for the compositions of Wolf motivated by the desire to use a solvent disclosed by the art as suitable for dissolving menthyl lactate.

In regards to the amounts recited in instant claims 8-10, Wolf discloses the cooling agents' concentration will depend on the intensity of the physiological cooling agent and the desired cooling effect. The reference also discloses that combinations of cooling agents may have synergistic effects. It would take no more than the relative skill of one of ordinary skill in the art to have adjusted the menthyl lactate to a concentration of 50 to 60%, menthol carboxamide to 10 to 20% and the solvent to 25 to 30% motivated by the desire to obtain a composition with the desired cooling effect.

Obvious-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 1-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16 and 22 of U.S. Patent No. 7,414,152 in view of Wolf (WO 99/13734) in view of H&R (Frescolat Cooling Ingredients 1999). The claims are not identical but they encompass overlapping subject matter. The patented claims encompass a product comprising a mixture of menthyl lactate and N-ethyl p-methanecarboxamide (WS-3 or menthol carboxamide). The instant claims recite a method of making a composition, a composition and products comprising that composition comprising WS-3 and menthyl lactate. The patented claims differ from the pending claims insofar as they are broader in scope by encompassing other cooling agent combinations and it does not disclose liquefying menthyl lactate before incorporating into a solution with menthol carboxamide.

Wolf discloses a method of making a solution of two or more cooling agents with a solvent. H&R disclose melting menthyl lactate before adding them to a product.

It would have been obvious to one of ordinary skill in the art to have used a combination of WS-3 and menthyl lactate with the process of the instant claims

in the compositions of the patented claims motivated by the desire to use a process that is suggested by the prior art.

2) Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 17 of copending Application No. 12/090801 in view of Wolf (WO 99/13734) in view of H&R (Frescolat Cooling Ingredients 1999). The claims are not identical but they encompass overlapping subject matter. The copending claims encompass a product comprising a mixture of menthyl lactate and WS-3 (menthol carboxamide). The instant claims recite a method of making a composition, a composition and products comprising that composition comprising WS-3 and menthyl lactate. The copending claims differ from the instant claims insofar as they are broader in scope by encompassing other cooling agent combinations and it does not disclose liquefying menthyl lactate before incorporating into a solution with menthol carboxamide.

Wolf discloses a method of making a solution of two or more cooling agents with a solvent. H&R disclose melting menthyl lactate before adding them to a product.

It would have been obvious to one of ordinary skill in the art to have used a combination of WS-3 and menthyl lactate with the process of the instant claims in the compositions of the copending claims motivated by the desire to use a process that is suggested by the prior art.

This is a provisional obviousness-type double patenting rejection.

3) Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 12/282,349; and claim 15 of copending Application No. 11/1990561 in view of Wolf (WO 99/13734) in view of H&R (Frescolat Cooling Ingredients 1999). The claims are not identical but they encompass overlapping subject matter. Both the copending claims encompass a product comprising a mixture of menthyl lactate and WS-3 (menthol carboxamide). The instant claims recite a method of making a composition, a composition and products comprising that composition comprising WS-3 and menthyl lactate. The copending claims differ from the instant claims insofar as they are broader in scope by encompassing other cooling agent combinations and it does not disclose liquefying menthyl lactate before incorporating into a solution with menthol carboxamide.

Wolf discloses a method of making a solution of two or more cooling agents with a solvent. H&R disclose melting menthyl lactate before adding them to a product.

It would have been obvious to one of ordinary skill in the art to have used a combination of WS-3 and menthyl lactate with the process of the instant claims in the compositions of the copending claims motivated by the desire to use a process that is suggested by the prior art.

This is a provisional obviousness-type double patenting rejection.

Claims 1-18 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612